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| APPLICATION NO.                           | FILING DATE           | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|---|-----------------------|----------------------|-------------------------|------------------|
| 10/542,386                                | . 11/30/2005          | Roni Zvuloni         | 30241                   | 5525             |
| Martin Moyniha                            | 7590 01/08/2008<br>an |                      | EXAM                    | INER             |
| Anthony Castorina                         |                       |                      | . BOR, HELENE CATHERINE |                  |
| Suite 207<br>2001 Jefferson Davis Highway |                       |                      | ART UNIT                | PAPER NUMBER     |
| Arlington, VA 22202                       |                       |                      | 3768                    |                  |
|   |                       |                      | ·                       |                  |
|   |                       |                      | MAIL DATE               | DELIVERY MODE    |
|   |                       |                      | 01/08/2008              | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|   | Application No.   | Applicant(s)   |  |  |  |  |
|---|---|--|--|--|--|--|
|   | 10/542,386  | ZVULONI, RONI  |  |  |  |  |
| Office Action Summary   | Examiner  | Art Unit   |  |  |  |  |
|   | Helene Bor  | 3768   |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address   |   |  |  |  |  |  |
| Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS,   |   |  |  |  |  |  |
| WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). |  |  |  |  |
| Status  |   |  |  |  |  |  |
| 1) Responsive to communication(s) filed on 09 Oc  | Responsive to communication(s) filed on <u>09 October 2007</u> .  |  |  |  |  |  |
| •   | This action is <b>FINAL</b> . 2b)⊠ This action is non-final.  |  |  |  |  |  |
| , —   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is   |  |  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.   |   |  |  |  |  |  |
| Disposition of Claims   |   |  |  |  |  |  |
| 4) Claim(s) <u>1-41</u> is/are pending in the application.  |   |  |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  |   |  |  |  |  |  |
| 5) Claim(s) is/are allowed.   |   |  |  |  |  |  |
| 6)⊠ Claim(s) <u>1-41</u> is/are rejected. 7)□ Claim(s) is/are objected to.  |   |  |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or   | election requirement.   |  |  |  |  |  |
|   | ·   |  |  |  |  |  |
| Application Papers  |   |  |  |  |  |  |
| 9) The specification is objected to by the Examiner.  |   |  |  |  |  |  |
| 10) The drawing(s) filed on <u>09 October 2007</u> is/are:  | • • • •   | •  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |   |  |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |   |  |  |  |  |  |
| Priority under 35 U.S.C. § 119  |   |  |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |   |  |  |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:  |   |  |  |  |  |  |
| 1. Certified copies of the priority documents have been received.   |   |  |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No  |   |  |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage   |   |  |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).   |   |  |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.  |   |  |  |  |  |  |
|   |   |  |  |  |  |  |
|   |   |  |  |  |  |  |
| Attachment(s)   |   |  |  |  |  |  |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date.   |   |  |  |  |  |  |
| ) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application  Other:  |   |  |  |  |  |  |
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### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

# Claim Rejections - 35 USC § 102

- 2. Claim 1, 3, 5-7, 9 & 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Murphy (US Patent No. 5,902,308).
- Claim 1: Murphy teaches a balloon catheter (Figure 5, Element 60) comprising a plurality of conductor bands [strain gauges] which vary in electrical resistance with the balloon circumference (Col. 5, Line 59-60 & Col. 9, Line 12-14).
- Claim 3: Murphy teaches the conductor bands are mounted internally to the balloon wall (Col. 9, Line 30-32).
- Claim 5 & 6: Murphy teaches the plurality of conductor bands mounted in a circumferential configuration (Figure 5, Element 62) and mounted in a plurality of circumferential configuration (Figure 5, Element 62).
- Claim 7: Murphy teaches the radio-opaque markers (Col. 5, Line 52-65 & Col. 8, Line 49-54).
- Claim 9: Murphy teaches an ultrasound marker distinguishable under ultrasound imaging (Col. 5, Line 52-60).
- Claim 11: Murphy teaches the conductor bands having a wire connection (Col. 6, Line 66).

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## Claim Rejections - 35 USC § 103

- 3. Claim 2, 4, 8 & 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murphy (US Patent No. 5,902,308) as applied to claim 1 above, and further in view of Knowlton et al. (US Patent No. 6,427,089).
- Claim 2 & 4: Murphy teaches the conductor bands are mounted internally to the balloon wall (Col. 9, Line 30-32). Murphy also teaches a sensor capable of being attached to the external surface of the balloon (Col. 5, Line 40). Murphy does not teach the sensor being embedded the in the balloon wall. However, Knowlton teaches a sensor being embedded in the balloon wall (Col. 15, Line 6-10) as an alternate equivalent manner to connect the wall and sensor. Thus it would have been obvious to one of ordinary skill in the art to modify the system of Murphy by including the wall sensor being embedded in the balloon as taught by Knowlton as alternate equivalent manner to connect the wall and sensor.
- Claim 8 & 10: Murphy teaches an ultrasound marker distinguishable under ultrasound imaging (Col. 5, Line 52-60) and teaches the radio-opaque markers (Col. 5, Line 52-65 & Col. 8, Line 49-54). Murphy fails to teach the asymmetric configuration of the markers. However, Knowlton teaches at least portions of the apparatus is radiopaque and visible under fluoroscopy and/or echogenic to be visible under ultrasonography (Col. 6, Line 66 Col. 7, Line 1) as an alternate equivalent manner to image a marker. Thus it would have been obvious to one of ordinary skill in the art to modify the system of Murphy by including the wall sensor being embedding in the balloon as taught by Knowlton as alternate equivalent manner to image a marker.

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4. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Murphy (US Patent No. 5,902,308) as applied to claim 1 above, and further in view of Holmes et al. (US Patent No. 4,873,990).

Claim 12: Murphy teaches the conductor bands having a wire connection (Col. 6, Line 66). Murphy fails to teach a wireless connection used by the conductor bands for reporting. However, Holmes teaches a device wherein the strain gauges are operable to report strain through telemetry [wireless connection] (Col. 4, Line 30-36) in order to provide information to remote equipment for monitoring (Col. 4, Line 38-36). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Murphy to include the wireless connection as taught by Holmes in order to provide information to remote equipment for monitoring (Col. 4, Line 38-36).

Claim 13-14, 19-23, 27 15-17, 34-36, 38 & 40 are rejected under 35
 U.S.C. 103(a) as being unpatentable over Murphy (US Patent No. 5,902,308), and further in view of Shah (US Patent No. 6,081,737).

Claim 13-14, 19-23 & 27: Murphy teaches a balloon catheter (Figure 5, Element 60) comprising a plurality of conductor bands [strain gauges] which vary in electrical resistance with the balloon circumference (Col. 5, Line 59-60 & Col. 9, Line 12-14). Murphy teaches expanding a balloon within a blood vessel (Col. 3, Line 60-63). Murphy teaches the device is very useful in the measurement of vascular stenoses [obstructions] (Col. 5, Line 51-52). Stenosis is being defined as "narrowing of a normal passage" or analogs to an obstruction. Murphy teaches conductor bands to provide information on the balloon cross-section in more than one target location (Col. 9, Line

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66).

30-35). Thus the method as taught by Murphy can report less expansion in local portions of the balloon by the conductor bands. Murphy fails to teach the data analysis aspect of the invention such as comparing the expansions reported by the conductor bands or recording the data in a memory module. However, Shah also teaches a method of data analysis as the comparing expansions reported by a plurality of strain gauges and recording the data in a memory module (Col. 6, Line 18-34 & Figure 8, Element 52 & 53) to display a more useful information to the operator such a map topology for assessing the efficacy of treatment (Col. 3, Line 38-44). It would have been obvious to one of ordinary skill in the art to modify the system of Murphy to include the data analysis as taught by Shah to display a more useful information to the operator such a map topology for assessing the efficacy of treatment (Col. 3, Line 38-44). Claim 15-17, 36 & 38: Murphy teaches the radio-opaque markers (Col. 5, Line 52-65 & Col. 8, Line 49-54) and observing the balloon by fluoroscopy [x-ray] (Col. 5, Line 17-21). Murphy teaches an ultrasound marker distinguishable under ultrasound imaging (Col. 5, Line 52-60) and observing the balloon by ultrasound (Col. 5, Line 17-21). Claim 34-35: Murphy teaches the plurality of conductor bands mounted in a circumferential configuration (Figure 5, Element 62) and mounted in a plurality of circumferential configuration (Figure 5, Element 62).

6. Claim 18 & 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murphy (US Patent No. 5,902,308) and Shah (US Patent No. 6,081,737) as

Claim 40: Murphy teaches the conductor bands having a wire connection (Col. 6, Line

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applied to claim 13 above, and further in view of Strommer 548 et al. (US Patent Application No. 2004/0138548).

Claim 18 & 24-30: Murphy teaches imaging techniques such as ultrasound and fluoroscopy (Col. 5, Line 55-56). Shah teaches displaying a three-dimensional map of the topology of the diseased section of the body lumen (Col. 7, Line 1-3). Murphy and Shah fail to teach to teach image integration of the images. However, Strommer teaches integration of two images from two different imaging modalities (Abstract & Page 2, Para 0013). It would have been obvious to one of ordinary skill in the art to modify the system of Murphy and Shah to include the image combining as taught by Strommer in order to view the location and orientation of the medical intervention device (e.g., catheter, needle) within the body of the patient during the operation (Page 1, Para 0002).

7. Claim 31, 33, 37 & 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murphy (US Patent No. 5,902,308) and Shah (US Patent No. 6,081,737) as applied to claim 19 above, and further in view of Knowlton et al. (US Patent No. 6,427,089).

Claim 31 & 33: Murphy teaches the conductor bands are mounted internally to the balloon wall (Col. 9, Line 30-32). Murphy also teaches a sensor capable of being attached to the external surface of the balloon (Col. 5, Line 40). Murphy does not teach the sensor being embedded the in the balloon wall. However, Knowlton teaches a sensor being embedded in the balloon wall (Col. 15, Line 6-10) as an alternate equivalent manner to connect the wall and sensor. Thus it would have been obvious to

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one of ordinary skill in the art to modify the system of Murphy by including the wall sensor being embedded in the balloon as taught by Knowlton as alternate equivalent manner to connect the wall and sensor.

Claim 37 & 39: Murphy teaches an ultrasound marker distinguishable under ultrasound imaging (Col. 5, Line 52-60) and teaches the radio-opaque markers (Col. 5, Line 52-65 & Col. 8, Line 49-54). Murphy fails to teach the asymmetric configuration of the markers. However, Knowlton teaches at least portions of the apparatus is radiopaque and visible under fluoroscopy and/or echogenic to be visible under ultrasonography (Col. 6, Line 66 - Col. 7, Line 1) as an alternate equivalent manner to image a marker. Thus it would have been obvious to one of ordinary skill in the art to modify the system of Murphy by including the wall sensor being embedded in the balloon as taught by Knowlton as alternate equivalent manner to image a marker.

8. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Murphy (US Patent No. 5,902,308) and Shah (US Patent No. 6,081,737) as applied to claim 41 above, and further in view of Holmes et al. (US Patent No. 4,873,990).

Claim 41: Murphy teaches the conductor bands having a wire connection (Col. 6, Line 66). Murphy fails to teach a wireless connection used by the conductor bands for reporting. However, Holmes teaches a device wherein the strain gauges are operable to report strain through telemetry [wireless connection] (Col. 4, Line 30-36) in order to provide information to remote equipment for monitoring (Col. 4, Line 38-36). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify

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the system of Murphy to include the wireless connection as taught by Holmes in order to provide information to remote equipment for monitoring (Col. 4, Line 38-36).

### Response to Arguments

- 9. Applicant's corrections, filed 10/09/2007, with respect to the drawings have been fully considered and therefor the objection has been withdrawn.
- 10. Applicant's arguments, see Page 3, filed 10/09/2007, with respect to the rejection(s) of claim(s) 1-41 under 35 U.S.C. § 102(b) and 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Murphy (US Patent No. 5,902,308).

### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helene Bor whose telephone number is 571-272-2947. The examiner can normally be reached on M-T 8:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

hcb -

ERICE WINAKUR PRIMARY EXAMMER